AO 120 (Rev. 3/04)

TO:	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court Southern District of Ohio on the following ☑ Patents or ☐ Trademarks:

DOCKET NO. 1:08-cv-078	DATE FILED 2/4/2008	U.S. DISTRICT COURT Southern District of Ohio
PLAINTIFF Forest Laboratories, Inc., et al.		DEFENDANT Kendle International Inc.

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	5,061,703		SEE ATTACHED COMPLAINT
2			
3			
4			
5			

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		SEE ATTACHED COMPLAINT
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK JAMES BONINI	(BY) DEPUTY CLERK s/Tempann Thomas	DATE 2/6/2008

Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., MERZ PHARMA GMBH & CO. KGAA, and MERZ PHARMACEUTICALS GMBH,

Plaintiffs,

vs.

KENDLE INTERNATIONAL INC.,

Defendant.

Civil Action No. 1:08 cv 78

COMPLAINT

Plaintiffs Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH (collectively "Plaintiffs") for their Complaint against Defendant Kendle International Inc. hereby allege as follows:

PARTIES

1. Plaintiff Forest Laboratories, Inc. ("Forest Labs") is a Delaware corporation having a principal place of business at 909 Third Avenue, New York, New York 10022.

2. Plaintiff Forest Laboratories Holdings, Ltd. is an Irish corporation having a principal place of business at Milner House, 18 Parliament Street, Hamilton JM11, Bermuda (referred to herein, together with Forest Laboratories, Inc., as "Forest").

(2)

3. Plaintiff Merz Pharma GmbH & Co. KGaA is a German corporation having a principal place of business at Eckenheimer Landstraße 100, D-60318 Frankfurt am Main, Germany.

4. Plaintiff Merz Pharmaceuticals GmbH is a German corporation having a principal place of business at Eckenheimer Landstraße 100, D-60318 Frankfurt am Main, Germany (referred to herein, together with Merz Pharma GmbH & Co. KGaA, as "Merz").

5. Upon information and belief, Defendant Kendle International Inc. ("Kendle") is an Ohio corporation having a principal place of business at 441 Vine Street, Suite 1200, Cincinnati, Ohio 45202. Upon information and belief, Defendant Kendle conducts business throughout the United States, including in this judicial district.

NATURE OF THE ACTION

6. This is a civil action for infringement of United States Patent No. 5,061,703 ("the '703 patent") (Exhibit A). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Defendant Kendle by virtue of the fact that, *inter alia*, Kendle has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including a corporation, Plaintiff Forest Labs, which manufactures numerous drugs for sale and use throughout the United States, including in this judicial district. This Court has personal jurisdiction over Kendle for the additional reason set

forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

9. This Court has personal jurisdiction over Defendant Kendle by virtue of the fact that, *inter alia*, Kendle is an Ohio corporation.

10. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENT-IN-SUIT

11. On October 29, 1991, the '703 patent, titled "Adamantane Derivatives in the Prevention and Treatment of Cerebral Ischemia," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). Merz has been, and continues to be, the sole assignee of the '703 patent since its issuance.

12. Forest is the exclusive licensee of the '703 patent in the United States. Forest holds New Drug Application ("NDA") No. 21-487 for Namenda® brand memantine hydrochloride tablets. The '703 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for Namenda®.

13. Forest is the exclusive distributor of Namenda® in the United States.

14. On August 18, 2004, Merz submitted a request to the PTO for reexamination of the '703 patent. The PTO issued a reexamination certificate (Exhibit B) for the '703 patent on November 7, 2006.

ACTS GIVING RISE TO THIS ACTION

Count I – Infringement Of The '703 Patent By Defendant Kendle

15. Upon information and belief, Defendant Kendle, on behalf of its principal Sun India Pharmaceutical Industries Limited ("Sun India") (a/k/a Sun Pharmaceutical Industries Limited), submitted ANDA No. 90-058 to the FDA under § 505(j) of the Federal Food, Drug and

Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use and sale of generic tablet products containing 5 milligrams and 10 milligrams of memantine hydrochloride ("the Sun Generic Products"). ANDA No. 90-058 specifically seeks FDA approval to market the Sun Generic Products prior to the expiration of the '703 patent.

16. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Kendle alleged in ANDA No. 90-058, on behalf of its principal Sun India, that the claims of the '703 patent are invalid, unenforceable and/or not infringed by the commercial manufacture, use or sale of the Sun Generic Products. Plaintiffs received written notification of ANDA No. 90-058 and its § 505(j)(2)(A)(vii)(IV) allegation on or about December 20, 2007.

17. Kendle's submission of ANDA No. 90-058 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Kendle commercially manufactures, uses, offers to sell, sells, or imports any of the Sun Generic Products, or induces or contributes to any such conduct, it would further infringe the '703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

18. Kendle was aware of the '703 patent prior to filing ANDA No. 90-058.

19. Kendle's actions render this an exceptional case under 35 U.S.C. § 285.

20. Plaintiffs will be irreparably harmed by Kendle's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

21. Plaintiffs have sought to enjoin Defendant Kendle's infringing activities as part of an action to enjoin acts of infringement of the '703 patent by numerous defendants filed by Plaintiffs in the District of Delaware on January 25, 2008, Civil Action No. 1:08-CV-00052.

Defendant Kendle is properly subject to personal jurisdiction in the District of Delaware and judicial economy would be promoted if all of Plaintiffs' claims for infringement of the '703 patent are addressed in the District of Delaware. Upon information and belief, Plaintiffs understand that Defendant may nevertheless contest jurisdiction in that venue. Given the possible consequences if Defendant succeeded with such unjustified action, Plaintiffs had no choice but to file this Complaint. In the event that Defendant is unsuccessful in any such challenge, Plaintiffs will dismiss this action.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Defendant Kendle has infringed the '703 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 90-058 identified in this Complaint shall not be earlier than the expiration date of the '703 patent, including any extensions;

C. That Defendant, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, selling, or importing any of the proposed generic versions of Plaintiffs' Namenda® brand product identified in this Complaint and any other product that infringes or induces or contributes to the infringement of the '703 patent, prior to the expiration of the '703 patent, including any extensions;

D. That this case is exceptional under 35 U.S.C. § 285;

E. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur prosecuting this action; and

F. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

Dated: February 4, 2008

Respectfully submitted,

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